Remarks: Claim Amendments

Claims 1, 3, and 5-8 were amended to correct the informalities noted by the Examiner and to more distinctly recite the claimed invention. Claim 4 was cancelled. Claims 10-18 are noted as Withdrawn.

Remarks: Examination Report

Claims 1-9 were rejected under 35 U.S.C. 112, second paragraph as being indefinite.

Specifically, Claim 1 was rejected because the term "glandular agent" was ruled to be vague and indefinite.

Claim 1 was amended to address this rejection, and the term "glandular agent" was replaced with a first component containing Gonadotrophin-releasing hormone. The importance of how Gonadotropin-releasing hormone relates to breast growth is described in the specification, such as in paragraph 16. Furthermore, it is well known in the art that bovine ovary contains Gonadotrophin-releasing hormone, such as described in Aten, R.F., Ireland, J.J., Weems, C.W. *et al.* (1987) "Presence of gonadotropin-releasing hormone like protein in bovine and ovine ovaries," *Endocrinology*, **120**, 1727–1733.

Claim 1 was rejected because the term "pituitary extract" was ruled to be vague and indefinite.

Claim 1 was amended to address this rejection, and the term "pituitary extract" was replaced with a third component comprising Prolactin. The association of Prolactin with the pituitary gland, and the importance of Prolactin for breast development is well known and is recited in the specification, such as in paragraph 16.

Claim 1 was rejected because the term "derivatives" was ruled to be vague and indefinite.

Claim 1 was amended to address this rejection, and the term "derivative" was removed.

Claims 1-7 were rejected under 35 U.S.C. 112, first paragraph as being indefinite because there is no guidance on or exemplification in the specification to prepare the claimed composition to increase breast size in a subject.

Applicant respectfully notes that none of the Claims 1-7 recites a function pertaining to increasing breast size. Instead, the independent Claim 1 recites a composition comprising a first component containing Gonadotrophin-releasing hormone; a second component comprising kelp; and a third component comprising Prolactin.

Furthermore, the specification teaches an embodiment having specific amounts of each component: "the composition comprises 75-90% by weight a glandular agent, 5-24% by weight a pituitary extract, and 1-5% by weight a kelp derivative." Paragraph 10.

The specification is also rather specific about each component. For example, the kelp component may comprise the dried thallus or the fresh thallus of bladderwrack kelp (paragraph 11 of the specification), and the ground particle size of kelp useful in compositions of the invention is about 0.1-20 μm, or 0.2-10 μm, but is typically about 0.2-5 μm (paragraph 12 of the specification).

Paragraph 15 describes the glandular agents (e.g., bovine ovary or pituitary gland), which are from non-human mammalian sources (e.g., bovine or porcine), and they are typically lyophilized (freeze-dried in the raw state).

The Examiner asserts that the prior art does not recognize the composition comprising a glandular agent, a kelp derivative, and a pituitary extract, as increasing breast size. The Examiner notes that the state of the prior art does not recognize each individual claimed active ingredient within the claimed composition as increasing breast size in a subject.

Specifically, the Examiner notes that Civelli (US 6,383,764) teaches that prolactin releasing peptides of the pituitary controls absence seizures, and Fleischner (US 6,503,529) teaches that bladderwrack kelp regulates thyroid functions.

The prior art does, in fact, describe the efficacy of each of the claimed components for increasing breast size.

1. The cited references Civelli mentions prolactin's role in mammary development:

"*PrRP was originally identified as a peptide having the physiological role of promoting the release of prolactin, a hormone involved in mammary development and lactation, from the anterior pituitary* (*Hinuma et al., Nature 393:272-276 (1998)*)." (US 6,383,764, Col. 6, lines 3-7).

2. Fleischner teaches the use of Bladderwrack Kelp to regulate thyroid function, thus regulating weight, which is a significant factor in breast size:

"*Bladderwrack kelp helps to regulate thyroid functions, as it is a source of iodine. Iodine is necessary to regulate hormone production. Low levels of thyroid hormone lead to hypothyroidism.*" US 6,503,529, col. 7, lines 46-50.

The structure of the breast is divided into the functional glandular element (comprising the milk ducts and support tissues) and fat. Thus, regulation of metabolism regulates the burning of fat, thereby affecting the mass and size of the breast.

Gonadotrophin-releasing hormone is used for contraception, and thus, causes side-effects that are similar to other drug-induced contraceptions, including increased breast size.

Ramey (US. 20030108586) describes administering Gonadotrophin-releasing hormone (GnRH) for contraception in animals. Specifically, when native GnRH is administered in a continuous drug-like fashion, there is GnRH receptor complex internalization (loss) resulting in "down-regulation" of pituitary GnRH. The pituitary becomes subsequently desensitized (unresponsive), leading to decreased synthesis and secretion of gonadotropins. Clinically, the result is the development of iatrogenic (drug induced) hypogonadotropic hypogonadism; i.e., reversible sterility.

It is well known that the use of contraceptive pills actually helps retain fluids in the breast. It might also have something to do with the pill affecting the hormones, resulting in an increase in breast size ( ).
Since contraceptive pills contain progesterone (or may induce the production of progesterone), they prevent ovulation.

Normally, when a menstrual cycle begins, the mammary glands undergo cyclical changes: in the second half of the cycle, under the increasing influence of progesterone, the glandular tissue grows. When conception does occur, the breasts continue to develop. The accompanying increase in blood supply distends the veins under the skin — often the first outward and visible sign of pregnancy. The glandular tissue proliferates, taking the place of connective tissue and fat, and the breasts progressively enlarge.

Thus, the prior art has linked increased progesterone levels due to drug induced contraception to breast enlargement.

Conclusion

The Applicant submits that every effort has been made to address the Examiner's objections and that the Application is now in condition to proceed to grant.

Yours Respectfully,

Steve J. Shattil
P.O. Box 17355
Boulder, CO 80308-0355
(720) 234-4351